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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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R. DOUGLAS BRADLEY
MERCK & CO. INC. PATENT DEPT
P.O. BOX 2000
RY60-30
RAHWAY, NJ 07065-0907

EXAMINER
ARCHIE, NINA

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Re-Mail

IPW

Office Action Summary	Application No.	Applicant(s)	
	10/566,426	PHILLIPS, JOHN W.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15,17,19-23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13,15,17,19-23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/2007 and 3/3/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

The information disclosure statements filed on 3/23/2007 and 3/3/2008 have been considered. Initialed copies are enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 13, 15, 17, 19, 20-23, and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claims recite, a method in step (b), with said recitation, "target polynucleotide being a sequence operatively linked to a promoter native to S. cerevisiae gene YMR325W, or a YMR325W promoter sequence homolog comprising one or more

nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote transcription of said operatively linked sequence". However, for a promoter to function there must be elements present which guide transcription. While there were many promoters and the elements therefrom known in the art, the promoters of the present invention must be associated with a gene which encodes an enzyme or regulator in the sterol biosynthesis pathway to be functional in a useful way in the invention. The term "homolog" is not defined in the specification, and does not have a precise meaning in the art (see the rejection, below, under 35 USC § 112, second paragraph), and is thus interpreted as reading upon any promoter possessing any degree of similarity to the specifically recited promoters, which thus represents a vast genus. Furthermore, there is no description in the specification of any structural features that would permit any given promoter to function in a relevant way in the present invention. As such, the genus of potential promoter sequences

Furthermore, the instant claims are drawn to a vast genus of homologs thereof of SEQ ID NO: 3. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of homologs thereof of SEQ ID NO: 3, applicant must also give a functional limitation of homologs thereof of SEQ ID NO: 3.

The specification, however, does not disclose distinguishing and identifying features of a representative member of the genus of homologs thereof of SEQ ID NO: 3 to which the claims are drawn, such as a correlation between structure of the peptide and its recited function, so that the skilled artisan could immediately envision or recognize at least a substantial number of members of the claimed genus of homologs thereof of SEQ ID NO: 3.

MPEP § 2163.02 states, "an objective standard for determining compliance with

the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". The courts have decided: The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. See Vas-Cath, Inc.'v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, "'Written Description" Requirement (66 FR 1099-1111, January 5,2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (Id. at 1104).

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing

predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Therefore, in accordance with the Guidelines, the description of homologs thereof of SEQ ID NO: 3 is not deemed representative of the genus of SEQ ID NO: 3 of the claim invention thus the claim does not meet the written description requirement.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-9, 13, 15, 17, 19, 21, 23, 25, and 28-30 rejected under 35 U.S.C. 102(e) as being unpatentable over Dixon et al US Patent No. 6828092 B1 Date December 7, 2004 US Filing Date January 12, 1998.

Examiner interprets homolog comprising one ore more nucleotide subsitutions, addition or deletion to be any promoter sequence.

Claims 1-3, 5-9, 13, 15, 17, 19, 21, 23, 25, and 28-30 are drawn to a method for determining whether a molecule affects the function or activity of a sterol biosynthesis pathway in a S. cerevisiae cell comprising: (a) contacting said cell with, or recombinantly expressing within said cell, said molecule; (b) determining whether RNA expression or protein expression in said cell of a target polynucleotide sequence is changed in step (a) relative to the expression of said target polynucleotide sequence in the absence of said molecule, said target polynucleotide being a sequence operatively linked to a promoter native to S. cerevisiae gene YMR325W, or a YMR325W promoter homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote transcription of said operatively linked sequence; and (c)
determining that said molecule affects the function or activity of said sterol biosynthesis pathway if expression of said target polynucleotide is changed, or determining that said molecule does not affect the function or activity of said sterol biosynthesis pathway if expression of said target polynucleotide sequence is unchanged (claim 1); a method for monitoring activity of a sterol biosynthesis pathway in a S. cerevisiae cell exposed to a molecule comprising: (a) contacting said cell with, or recombinantly expressing within said cell, said molecule; (b) determining whether RNA expression or protein expression in said cell of a target polynucleotide sequence is changed in step (a) relative to expression of said target polynucleotide sequence in the absence of said molecule, said target polynucleotide sequence being regulated by a promoter native to a S. cerevisiae YMR325W gene or a YMR325W homolog comprising one or more nucleotide substitutions, additions or deletion that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence; and (c) determining that the activity of the sterol biosynthesis pathway in said cell is changed if expression of said target polynucleotide is determined to be changed in step (b), or determining that the activity of the sterol biosynthesis pathway in said cell is unchanged if expression of said target polynucleotide is determined to be unchanged in

step (b) (claim 13); a method for identifying a molecule that modulates expression of a sterol biosynthesis pathway target polynucleotide sequence comprising: (a) recombinantly expressing in a S. cerevisiae cell, or contacting a S. cerevisiae cell with, at least one candidate molecule; and (b) measuring RNA or protein expression in said cell of a target polynucleotide sequence, said target polynucleotide sequence being regulated by a promoter native to a S. cerevisiae YMR325W gene or a YMR325W sequence homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence thereof ; wherein an increase or decrease in expression of said target polynucleotide sequence relative to expression of said target polynucleotide sequence in the absence of said candidate molecule indicates that said candidate molecule modulates expression of said sterol biosynthesis pathway target polynucleotide sequence (claim 22).

Dixon et al teach a method for the identification of agents which modulate sterol biosynthesis which method comprises contacting a test compound with a host cell of S. cerevisiae comprising a DNA sequence which controls expression of a yeast acetoacetyl CoA thiolase gene operably linked to a reporter system such that modulation of sterol biosynthesis in the host cell leads to a detectable change in cell phenotype, and determining whether any such detectable change has occurred (see abstract). Dixon et al teach one or more individual enzymes from the pathway are selected, and compounds are screened for their ability to inhibit these enzymes. Dixon et al teach that operably linked means linked in such a way as to provide the basic sequence signals necessary for initiation of gene transcription and initiation of gene translation. Dixon et al teach in vivo assays for inhibitors of sterol biosynthesis wherein inhibition leads to a change in the level of expression of a reporter gene and nucleic acids and recombinant cells use in the assays. Dixon et al teach that the activity of the reporter gene when grown under aerobic conditions in the absence of inhibitors of sterol biosynthesis is low. Dixon et al teach that the promoter region of S. cerevisiae acetoacetyl CoA thiolase is linked to a reporter gene the reporter gene may be induced by sterol biosynthesis inhibitors. Dixon et al teach an assay which is capable of

detecting a wide range of inhibitors of sterol biosynthesis and that the assay is simple, cheap and robust and may be employed in high throughput mode to screen large chemical collections, natural product collections and compound libraries. Dixon et al teach that the assay described here may be used in combination with another reporter system in the same cell, allowing for compounds to be simultaneously screened for the ability to modulate sterol biosynthesis and other processes. Dixon et al teach novel forms of green fluorescent proteins with different absorption spectra that allow the use of multifunctional assays in the cell using the same output. Dixon et al teach that the advantage of using a reporter gene as a reporter system is that it confers a readily measurable phenotype upon the cell and that the reporter gene may conveniently comprise the coding sequence of a enzyme such as firefly luciferase, E. coli choramphenicol acetyl transferase, or green fluorescent protein, in which the phenotype conferred may be measured by alterations in fluorescence (see abstract claims.

Thus Dixon et al teach a method for determining whether a molecule affects the function or activity and a method for monitoring activity of a sterol biosynthesis pathway in a S. cerevisiae cell comprising: (a) contacting said cell with, or recombinantly expressing within said cell, said molecule; (b) determining whether RNA expression or protein expression in said cell of a target polynucleotide sequence is changed in step (a) relative to the expression of said target polynucleotide sequence in the absence of said molecule, said target polynucleotide being a sequence operatively linked to a promoter native to S. cerevisiae gene YMR325W promoter homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote transcription of said operatively linked sequence thereof ; and (c) determining that said molecule affects the function or activity and a method of determining that the activity of said sterol biosynthesis pathway if expression of said target polynucleotide is changed, or determining that said molecule does not affect the function or activity of said sterol biosynthesis pathway if expression of said target polynucleotide sequence is unchanged, wherein said target polynucleotide sequence comprises a marker gene; wherein step (b) comprises determining whether the RNA expression or protein expression of said marker gene is changed in step (a) relative to

the expression of said marker gene in the absence of the molecule; and wherein step (c) comprises determining that said molecule affects the function or activity of said sterol biosynthesis pathway if expression of said marker gene is changed, or determining that said molecule does not affect the function or activity of said sterol biosynthesis pathway if expression of said marker gene is unchanged, wherein said molecule inhibits sterol biosynthesis such that said cell contacted with the molecule exhibits a lower level of sterol than a second cell which is not contacted with said molecule, wherein step (b) comprises determining whether RNA expression is changed, wherein step (b) comprises determining whether protein expression is changed, wherein step (c) comprises determining that said molecule inhibits sterol biosynthesis if expression of said target polynucleotide sequence in step (a) is increased relative to expression of said target polynucleotide sequence in the absence of said molecule, wherein the S. cerevisiae cell is a cell that recombinantly expresses said target polynucleotide sequence, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in a liquid high throughput-like assay, wherein said molecule are proteins.

Thus Dixon et al teach a method for identifying a molecule that modulates expression of a sterol biosynthesis pathway target polynucleotide sequence comprising: (a) recombinantly expressing in a S. cerevisiae cell, or contacting a S. cerevisiae cell with, at least one candidate molecule; and (b) measuring RNA or protein expression in said cell of a target polynucleotide sequence, said target polynucleotide sequence being regulated by a YMR325W sequence homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence; wherein an increase or decrease in expression of said target polynucleotide sequence relative to expression of said target polynucleotide sequence in the absence of said candidate molecule indicates that said candidate molecule modulates expression of said sterol biosynthesis pathway target polynucleotide sequence, wherein step (a) comprises contacting said cell with a second, test cell, wherein said test cell produces said molecule, wherein said molecule is released by said test cell, wherein said

molecule is secreted by said test cell (see abstract, claims, columns 1-2 and 5-10 and example 1).

Claims 1-11, 13, 15, 17, 19-23, and 25-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Dixon et al US Patent No. 6828092 B1 Date December 7, 2004 US Filing Date January 12, 1998 in view of Ashby et al WO/2000/58521 Date October 5, 2000, Phillips, J. US Patent No: 7022481B2 Date April 4, 2006 US Filing Date December 19, 2002, and Contreras et al. WO/2001/02550A2 Date January 11, 2001.

Claims 1-11, 13, 15, 17, 19-23, and 25-30 are drawn to A method for determining whether a molecule affects the function or activity of a sterol biosynthesis pathway in a S. cerevisiae cell comprising: (a) contacting said cell with, or recombinantly expressing within said cell, said molecule; (b) determining whether RNA expression or protein expression in said cell of a target polynucleotide sequence is changed in step (a) relative to the expression of said target polynucleotide sequence in the absence of said molecule, said target polynucleotide being a sequence operatively linked to a promoter native to S. cerevisiae gene YMR325W, or a YMR325W promoter homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote transcription of said operatively linked sequence; and (c) determining that said molecule affects the function or activity of said sterol biosynthesis pathway if expression of said target polynucleotide is changed, or determining that said molecule does not affect the function or activity of said sterol biosynthesis pathway if expression of said target polynucleotide sequence is unchanged (claim 1); a method for monitoring activity of a sterol biosynthesis pathway in a S. cerevisiae cell exposed to a molecule comprising: (a) contacting said cell with, or recombinantly expressing within said cell, said molecule; (b) determining whether RNA expression or protein expression in said cell of a target polynucleotide sequence is changed in step (a) relative to expression of said target polynucleotide sequence in the absence of said molecule, said target polynucleotide sequence being regulated by a promoter native to a S. cerevisiae YMR325W gene or a YMR325W homolog comprising one or more nucleotide substitutions, additions or deletion that do not effect the ability of the sequence to

promote regulated transcription of said target polynucleotide sequence; and (c) determining that the activity of the sterol biosynthesis pathway in said cell is changed if expression of said target polynucleotide is determined to be changed in step (b), or determining that the activity of the sterol biosynthesis pathway in said cell is unchanged if expression of said target polynucleotide is determined to be unchanged in step (b) (claim 13); a method for identifying a molecule that modulates expression of a sterol biosynthesis pathway target polynucleotide sequence comprising: (a) recombinantly expressing in a S. cerevisiae cell, or contacting a S. cerevisiae cell with, at least one candidate molecule; and (b) measuring RNA or protein expression in said cell of a target polynucleotide sequence, said target polynucleotide sequence being regulated by a promoter native to a S. cerevisiae YMR325W gene or a YMR325W sequence homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence thereof ; wherein an increase or decrease in expression of said target polynucleotide sequence relative to expression of said target polynucleotide sequence in the absence of said candidate molecule indicates that said candidate molecule modulates expression of said sterol biosynthesis pathway target polynucleotide sequence (claim 22).

Dixon is relied upon as set forth supra. However Dixon et al does not teach a method using YMR325W promoter, Dixon et al does not teach a method, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in a solid plate halo assay, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in an agar overlay assay, wherein said molecule is purified, wherein said molecule is not substantially purified, wherein said promoter comprises SEQ ID NO: 3 or a SE0 ID NO: 3 homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote transcription of said operatively linked sequence thereof.

Ashby teach methods of identifying genes whose expression is indicative of activation of a particular biochemical or metabolic pathway or a common set of biological reactions or functions in a cell ("regulon indicator genes"). Ashby et al teach

methods for identifying effectors (activators and inhibitors) of regulon target genes are provided. Ashby et al teach genes that are regulated by regulon target genes of yeast or its mammalian homolog may be identified comprising the steps of a) overexpressing the target gene in host cells of a matrix comprising a plurality of units of cells, the cells in each unit containing a reporter gene operably linked to an expression control sequence derived from a gene of a selected organism; and b) identifying genes that are either induced or repressed by overexpression of the target gene. Ashby et al teach yeast cells respond by significantly up-regulating the genes encoding sterol biosynthetic enzymes and thus synthesizing more of the enzymes that make sterols and identifying genes that are involved in sterol biosynthesis or in related metabolic pathways by assays (see abstract claims, pgs. 1 and 15-22).

Ashby et al teach an isolated protein or polypeptide that has been separated from naturally associated components that accompany it in its native state. Thus, a polypeptide that is chemically synthesized or synthesized in a cellular system different from the cell from which it naturally originates will be "isolated" from its naturally associated components. Ashby et al teach a protein may also be rendered substantially free of naturally associated components by isolation, using protein purification techniques well known in the art. Ashby et al teach a monomeric protein is "substantially pure, "substantially homogeneous" or "substantially purified" when at least about 60 to 75% of a sample exhibits a single polypeptide sequence. Ashby et al teach a substantially pure protein will typically comprise about 60 to 90% W/W of a protein sample, more usually about 95%, and preferably will be over 99% pure. Ashby et al teach a protein purity or homogeneity may be indicated by a number of means well known in the art, such as polyacrylamide gel electrophoresis of a protein sample, followed by visualizing a single polypeptide band upon staining the gel with a stain well known in the art and for certain purposes, higher resolution may be provided by using HPLC or other means well known in the art for purification. Ashby et al teach nucleic acids of this invention include single-stranded and double-stranded DNA, RNA, oligonucleotides, antisense molecules, or hybrids thereof and may be isolated from biological sources or synthesized chemically or by recombinant DNA methodology.

Ashby et al teach that the nucleic acids, recombinant DNA molecules and vectors of this invention may be present in transformed or transfected cells, cell lysates, or in partially purified or substantially pure forms (see abstract claims, pgs. 1 and 15-22).

Ashby et al teach S. cerevisiae proteins that have homology to a protein from another organism if the encoded amino acid sequence of the yeast protein has a similar sequence to the encoded amino acid sequence of a protein of a different of a different organism. Ashby et al teach a S. cerevisiae protein may have homology or be homologous to another S. cerevisiae protein if the two proteins have similar amino acid sequences (see abstract claims, pgs. 1 and 15-22). Thus teaching a method, wherein said molecule is purified, wherein said molecule is not substantially purified.

Phillips teach a method in a pathway in S. cerevisiae as set forth supra, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in a solid plate halo assay, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in an agar overlay assay (see claims).

Contreras et al. teach a sequence that is 98% identical to SEQ ID NO:3 thus teaching a YMR325W sequence homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence thereof (see claim 1 figure 1 STIC results).

It would have been prima facie obvious at the time the invention was made to incorporate a YMR325W sequence homolog comprising one or more nucleotide substitutions, additions or deletions that do not effect the ability of the sequence to promote regulated transcription of said target polynucleotide sequence thereof as taught by Contreras et al because Contreras et al teach protein and coding sequences of apoptosis associated proteins from the yeast Saccharomyces cerevisiae that can be used to identify treatments for yeast infections (see abstract). It would have been prima facie obvious at the time the invention was made to incorporate a method in a pathway in S. cerevisiae as set forth supra, wherein step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in a solid plate halo assay, wherein

step (a) comprises contacting said cell with said molecule, and wherein step (a) is carried out in an agar overlay assay as taught by Phillips J. because both Phillips and Dixon et al teach the same method of determining the function, monitoring, and identifying a molecule in a biosynthesis pathway of S. cerevisiae. It would have been prima facie obvious at the time the invention was made to incorporate a method, wherein said molecule is purified, wherein said molecule is not substantially purified as taught by Ashby et al because both Ashby et al and Dixon et al teach the same method of determining the function, monitoring, and identifying a molecule in a biosynthesis pathway of S. cerevisiae.

Status of the Claims

Claims 1-11, 13, 15, 17, 19-23, and 25-30 are rejected.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina Archie

Examiner

Art Unit 1645

/Nina A Archie/

Examiner, Art Unit 1645

/N. A. A./

Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645